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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,536	07/29/2003	Paula M. McCready	IL-11030	3210

7590 08/07/2006

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EXAMINER	
BAUSCH, SARAE L	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,536	MCCREADY ET AL.	
	Examiner	Art Unit	
	Sarae Bausch	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-17* is/are pending in the application.

4a) Of the above claim(s) *4-7,9,10 and 14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, newly added claims 8-14 in the reply filed on 06/12/2006 is acknowledged. The traversal is on the ground(s) that the new claims are drawn to at least two amplicons and believe the pending claims should be examined together as described in MPEP 803.04. This is not found persuasive because as stated in MPEP 803.04, applications containing composition claims reciting different combinations of individual nucleotide sequences will be subject to a restriction requirement and applicants will be required to select one combination for examination. Furthermore, as stated in the MPEP 803.04, the complex nature of the claimed material may necessitate the reasonable number of sequences to be less than ten. Searching a composition comprising any combination of 7 amplicons, requires search all 7 sequences and their resulting primers probe, which constitute a total of 25 sequences which is a significant number of sequences to examine. The office would have to search each combination of seven sequences in addition to all 18 sequences of primers and probes, which would be a search burden to the office as the demand on the PTO's computers dedicated to sequence searches alone would be undue as would the time the examiner would need to review the finding of all 25 searches. In the instant case, the search burden to examine up the combination of seven amplicons sequences is a search burden. Furthermore, the claimed nucleic acids lack unity of invention because the instantly claimed nucleic acids have different sequences and can be used to detect different sequences and therefore have different structure and function and lack unity of invention and therefore it is proper to restrict the patentably distinct and independent inventions under 35 USC 121.

2. Claims 4-7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/12/2006.

3. Applicant was required to pick a specific composition of sequences, as stated in the restriction requirement mailed 01/12/2006, however applicant did not elect a specific composition of sequences. During a telephone conversation with Susan Hubl on 06/29/2006 a provisional election was made with traverse to prosecute the invention of group I, the composition of SEQ ID No. 4 and 8, claims 8, 11-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-9 and 14-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicant representative elected with the caveat that if claim 8 was found to be allowable, claims 9-10 and 14-17 would be rejoined.

4. Claims 8, 11-13 and the specific combination of SEQ ID No. 4 and 8 and the set of oligonucleotides of SEQ ID No. 1, 2, 3, 5, 6, and 7 are under examination on the merits.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. The specification on page 6, paragraph 11 contains a hyperlink. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added claim(s) contain subject matter that changes the scope of the claim and is not supported in the specification and raises issues of new matter.

Newly added claims 11-13 with the recitation in claim 11 of "12 to 50 nucleotides in length" changes the scope of the claim and the recitation of 12 to 50 nucleotides in length of fragments of SEQ ID no. 4 and 8 is not supported in the specification and raises the issue of new matter. The specification does not teach any size for a fragment. The specification teaches SEQ ID No. 1-3 and 5-7 as fragments of SEQ ID No. 4 and 8, however SEQ ID No. 1-3 and 5-7 encompass fragment sizes of 23, 24, 28, and 33 nucleotides in length and do not encompass the claimed subgenus of 12 to 50 nucleotides in length. The specification provides no criticality of 12 to 50 nucleotides in length of a fragments of SEQ ID No. 4 and 8 and provides no example of any actual fragment which contains 12 to 50 nucleotides. There is no support in the specification to use 12 to 50 nucleotides in length of fragments of SEQ ID No. 4 and 8. As discussed in MPEP 2163.05, section III, with respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1328, 56 USPQ2d1481, 1487 (Fed. Cir. 2000) ("[T]he specification does not clearly disclose to the skilled artisan that the inventors.... considered the... ratio to be part of their invention.... There

is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion").

8. Claims 8, 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8 and 11-13 are drawn to a composition comprising a first isolated polynucleotide and a second isolated polynucleotide, the first isolated polynucleotide comprises SEQ ID No. 4 or full length complement thereof and the second isolated polynucleotide comprises SEQ ID No. 8 or full length complement thereof. While the specification teaches SEQ ID NO 4 and 8, the recitation of "comprises" is open language and "comprises" reads on full length genomic sequences from any source, as well as homologs and variants of Y. Pestis which are not taught or described by the specification. Furthermore, the recitation of "a" first isolated nucleic acid and "a" second isolated polynucleotide broadly encompasses variants, homologs, and mutants with a minimum of two nucleotides of SEQ ID No 4 and 8 from any source which are not taught or described by the specification.

Claim 11-13 are drawn to a set of oligonucleotides comprising a polynucleotide "fragment of each of the isolated polynucleotides of the composition of claim 8, wherein said fragments are 12 to 50 nucleotides in length" which broadly encompasses variants, mutants and homologs containing at least 12 nucleotides of SEQ ID NO 4 and 8 from any source. The

recitation of a fragment of isolated polynucleotides broadly encompasses substantial variation and altered sequences that broadly encompass variants, homologs, and mutants of SEQ ID No 4 and 8 from any source that are not taught in the specification

Claims 11-13 are drawn to a set of oligonucleotides comprising a fragment of 12 to 50 nucleotides in length of SEQ ID no. 4 and 8. Claim 13 recites a set of oligonucleotides wherein each oligonucleotide comprises one of SEQ ID no. 1-3, 5-7. While the specification teaches SEQ ID no. 1-3 and 5-7, the recitation of "comprises" is open language which reads on full length genomic sequences from any source, as well as homologs and variants of Y. Pestis that are not taught or described by the specification.

While the specification teaches SEQ ID NO 1-8, the specification provides insufficient written description to support the broad genus encompassed by the claims. The instant claims are drawn to undisclosed sequences encoding modification that have not been contemplated. The specification provides insufficient written description to support the genus encompassed by the claim. Absent a written description, the specification fails to show that the applicant was "in possession of the claimed invention" at the time the application for the patent was filed. Further, the genus of polynucleotides comprised by the claim is a large variable genus and also reads on undisclosed genomic sequences. The specification only discloses a selected number of species of the genus; i.e. SEQ ID NO 1-8, which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the genus, which include full length genes, mutants, variants, and homologs of Y. Pestis from any source. Thus one skilled in the art cannot reasonably conclude that applicant had possession of the claimed genomic sequences, as

well as mutants, variants, and homologs from any source at the time the instant application was filed with respect to claims 1-7, 15-24, 50 and 54.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of SEQ ID NO: 1-8; the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993), and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

> To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Accordingly, the specification does not provide written description of the invention of claims 8 and 11-13.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 8 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Hu et al. (J. Bacteriol. 1998, vol. 180, pages 5192-5202).

Hu et al. teach a composition comprising SEQ ID no. 1-8. With regard to claim 8, Hu et al. teach the sequence of pMT1 which comprises nucleotides 85237-85136 which are identical to SEQ ID No. 4 and nucleotides 13354-13500, which are identical to SEQ ID No. 8 (alignment provided). Therefore, pMT1 is a composition that comprises SEQ ID No. 4 and 8. With regard to claims 11, Hu et al. teach a composition that comprises a fragment that comprises 12 to 50 nucleotides (positions 85237-85136 and 13354-13500) that are completely complementary to instant SEQ ID No. 4 and 8. Therefore, the sequence within pMT1 taught by Hu et al. anticipates claims 8 and 11. With regard to claims 12 and 13, the sequence of Hu et al. is a fragment that comprises 12 to 50 nucleotides and comprises primers and probes of SEQ ID no. 4 and 8. Furthermore, the sequence of pMT1 taught by Hu et al. is a set of oligonucleotides

that comprises SEQ ID No. 1 (positions 85237-85210), 2(positions 85136-85163), 3(positions 85207-85175), 5 (positions 13354-13377), 6 (position 13500-13478), 7 (position 13379-13411) and therefore the sequence of pMT1 taught by Hu et al. anticipates claims 8, 11-13.

Conclusion

11. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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